

1. An oral solid pharmaceutical dosage form comprising an extended release (ER) tablet, wherein said ER tablet comprises:

- a. an effective amount of a macrolide antibiotic selected from clarithromycin, azithromycin, or an erythromycin derivative;

5                   b. from about 2% to about 40% w/w of one or more pharmaceutically acceptable water soluble excipients;

- c. one or more tableting aids;

- d. wherein the dosage form does not contain a dissolution rate controlling polymer; and

10                  e. wherein said tablet when tested in a USP Apparatus 2 at 50 rpm using 900 mL 0.1M sodium acetate buffer (pH=5.0) at 37°C exhibits a dissolution profile substantially corresponding to the following pattern:

not more than 35% of the total antibiotic is released in 2 hours;

about 30-60% of the total antibiotic is released in 4 hours;

15                   about 50-90% of the total antibiotic is released in 8 hours; and

not less than 70% of the total antibiotic is released in 12 hours.

2. A pharmaceutical dosage form as defined in claim 1, wherein said dissolution profile substantially corresponds to the following pattern:

not more than 30% of the total antibiotic is released in 2 hours;

about 30-50% of the total antibiotic is released in 4 hours;

5                   about 60-85% of the total antibiotic is released in 8 hours; and

8. A pharmaceutical dosage form as defined in claims 3 wherein said tableting aid is magnesium stearate alone or in combination with talc externally blended at a total concentration of from about 1.0 % to about 10 % by weight.
9. A pharmaceutical dosage form as defined in claims 1-3 wherein said tableting aid is colloidal silicon dioxide externally blended at a concentration of about 0.1-0.5 % by weight of total tablet weight.
10. A production method for the preparation of an extended release clarithromycin tablet, comprising the steps of:

- a. preparing a granulation of clarithromycin in a high shear granulator, comprising a pharmaceutically acceptable filler/diluent and an aqueous solution of a binder, optionally acidified using HCl for a normality of 0.005-0.05;
- b. blending said granulation with other non-dissolution rate controlling excipients selected from the group consisting of a glidant, talc, a filler, and a lubricant;
- c. compressing the blend to produce 500 mg or 1000 mg extended release clarithromycin tablets using a rotary tablet press;

wherein the tablet exhibits a dissolution profile that substantially corresponds to the following pattern:

not more than 35%, of the total clarithromycin is released in 2 hours;

about 30-60%, of the total clarithromycin is released in 4 hours;

about 50-90%, of the total clarithromycin is released in 8 hours; and

not less than 70%, of the total clarithromycin is released in 12 hours.

11. The method of claim 10 wherein said clarithromycin-containing tablet core may be provided with a film coat.

not less than 85% of the total antibiotic is released in 12 hours.

3. A pharmaceutical dosage form as defined in claim 2, wherein said tablet core is prepared by (1) granulating clarithromycin, at a concentration of from about 62% to about 90% w/w based on the total tablet weight with a pharmaceutically acceptable filler selected from the group consisting of lactose, mannitol, and microcrystalline cellulose, using an aqueous solution of a hydrophilic binder which is optionally acidified with hydrochloric acid to a normality ranging from about 0.005 to about 0.05, (2) blending said granules with a tableting aid selected from the group consisting of magnesium stearate, fine colloidal silicon dioxide, talc, microcrystalline cellulose and/or lactose, and (3) compressing the blend into 500 mg or 1000 mg tablets in the weight range of about 575 - 750 mg and 1120-1500 mg, respectively.
4. A pharmaceutical dosage form as defined in claim 1 wherein the pharmaceutically acceptable diluent in the granulation includes lactose at a concentration of from about 5% to about 35% w/w.
5. A pharmaceutical dosage form as defined in claim 4 wherein said hydrophilic binder is selected from the group consisting of polyvinylpyrrolidone, hydroxypropylmethylcellulose, hydroxypropylcellulose, corn, starch, and dextran for granulation at a concentration of from about 1% to about 4% w/w based on the total tablet weight, added either in the dry form or as an aqueous solution of a mineral acid.
6. A pharmaceutical dosage form as defined in claim 3 wherein said tableting aid includes lactose blended at a concentration of about 1-5 % by weight of total tablet weight.
7. A pharmaceutical dosage form as defined in claim 3 wherein said tableting aid includes microcrystalline cellulose blended at a concentration of about 1-4 % by weight for a total polymer content of not more than 5% by weight of the tablet.

12. The method of claim 10 wherein said dissolution profile substantially corresponds to the following pattern:

not more than about 30% of the total clarithromycin is released in 2 hours;

about 30-50% of the total clarithromycin is released in 4 hours;

5 about 60-85% of the total clarithromycin is released in 8 hours; and

not less than about 85% of the total clarithromycin is released in 12 hours.